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VIA CM/ECF AND HAND DELIVERY
The Honorable Jennifer L. Hall
J. Caleb Boggs Federal Building
Unit 17, Room 6312
844 North King Street
Wilmington, DE 19801-3555

April 25, 2026

Re: *Ingenus Pharmaceuticals, LLC v. Hetero USA, Inc. et al.*
C.A. No. 24-1025-JLH

Dear Judge Hall,

Defendants Hetero Labs Limited and Hetero Drugs Limited (collectively "Hetero") oppose Plaintiff's letter regarding alleged discovery deficiencies.

Plaintiff's discovery letter is premature. Hetero has already produced its ANDA and agreed to produce all documents related to the research and development of its ANDA product. This broad scope of production encompasses almost the entire universe of documents that could be relevant to this case, including the documents asked for in the requests that are the subject of Plaintiff's letter. During the parties' meet and confer, Hetero asked Plaintiff what legitimate documents in each category Plaintiff was seeking that would not be part of the research and development of its ANDA product. Plaintiff has not identified anything that would be outside of the scope Hetero agreed to produce (other than certain specific discrete categories, like organizational charts, addressed below).

Nor is Hetero withholding any documents subject to its objections at this time. We informed Plaintiff that Hetero was gathering documents to produce and would supplement its responses. Pls' Ex. 4, D.I. 41-4 at 3. Hetero also suggested that Plaintiff review Hetero's document production and the parties could revisit whether any additional documents would need to be produced, particularly given that it appeared that Plaintiff had not yet reviewed Hetero's ANDA at the time of the parties' meet and confer. Hetero also confirmed that there were no documents related to projected sales, marketing, or advertising. Pls' Ex. 4, D.I. 41-4 at 3. Hetero therefore has no documents responsive to Request Nos. 9-13. D.I. 41-2. Plaintiff nonetheless proceeded with its motion.

The relief requested in Plaintiff's letter should be denied. Plaintiff does not even attempt to demonstrate which, if any, of the discovery requests at issue are relevant or reasonably likely to lead to the discovery of admissible evidence.[1] Plaintiff's sole argument without any support, is

[1] In its letter regarding the discovery dispute, Plaintiff argues that "The relevancy standard in this Circuit is undemanding and liberal." D.I. 41 at 3. However, in response to Hetero's discovery letter, Plaintiff states that "Ingenus will produce responsive nonconfidential documents

that these types of documents "are routinely produced in ANDA litigations." Plaintiff has therefore not met its initial burden to compel any discovery. *Thompson-El v. Greater Dover Boys & Girls Club*, No. CV 18-1426-RGA, 2022 WL 606700, at *2 (D. Del. Jan. 28, 2022) ("A party moving to compel discovery bears the initial burden of establishing the relevance of the requested information.").

Moreover, Plaintiff served its "routine" requests without consideration of whether the information sought is relevant to the patent claims it is asserting in this litigation. For example, while it is true that documents related to Hetero's proposed label and package inserts (RFP Nos. 6-7) are routinely produced in ANDA cases involving method of treatment patents, they are not routinely sought or produced in cases where the sole asserted patent is a formulation patent. Hetero has already produced its proposed label and package insert as part of its ANDA. Plaintiff, however, fails to identify what more it could possibly want in response to these Requests.

Additionally, the Court should deny the relief sought by Plaintiff's discovery letter because Hetero has met its discovery obligations. Hetero has not, as Plaintiff suggests, refused to produce documents or insisted that it would rely only on its ANDA. As discussed above, Hetero agreed to produce all documents related to the research and development concerning ANDA No. 219271. D.I. 41-2 at Request No. 2. These documents, which Hetero has agreed to produce, encompass the vast majority of documents that could be relevant in this case and are also responsive to Request Nos. 5-8, 16, 21, 25-31, and 33-35. Hetero similarly agreed in its interrogatory responses to produce documents regarding research, testing, studies, development and manufacturing related to its ANDA Product (D.I. 41-3 at Interrogatory No. 2), its ANDA product formulation (*Id.* at Interrogatory No. 3), and testing (*Id.* at Interrogatory No. 11). Again, these are categories of documents actually relevant to the asserted claims rather than what Plaintiff calls "routine" requests not tailored to the needs of this case.

In addition, many of the requests at issue are not limited to the ANDA Product and ask for documents related to "any product containing cyclophosphamide." Hetero also properly limited its discovery responses to its proposed ANDA product. Information about other cyclophosphamide products is not relevant to this litigation (to the extent such information even exists within Hetero's possession, custody, and control). *See, for example, Par Pharm., Inc. v. Hospira, Inc.*, No. CV 17-944-JFB-SRF, 2019 WL 2354670, at *3 (D. Del. June 4, 2019) ("The Court finds no error in the Magistrate Judge's determination that the laboratory batch was not prepared as is specified in Hospira's ANDA and the samples were not representative of the ANDA product that would be sold pending approval of the ANDA and thus were not relevant evidence.") *See also Abbott Labs v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) ("An infringement inquiry provoked by an ANDA filing under 35 U.S.C. § 271(e)(2)(A) is focused on the product that is likely to be sold following FDA approval."); *Glaxo, Inc. v. Novopharm, Ltd.,*

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relevant to issues in this case, once Hetero identifies those issues." D.I. 38 at 4. Plaintiff provides no explanation for why it applies a different standard when it is responding to discovery.

110 F.3d 1562, 1568, 42 USPQ2d 1257, 1262 (Fed. Cir. 1997). Hetero therefore properly objected to the scope of Request Nos. 10, 13, 14, 16-18, 28, and 32-35.

Hetero did not agree to provide information and documents that are outside the scope of the litigation, which is focused on the ANDA itself. *See* 35 U.S.C.A. § 271(e)(2); *Abbott Labs.*, 300 F.3d at 1373 ("[A]n ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry.") Accordingly, decisions that took place prior to the ANDA (Request Nos. 23-24) are not relevant or likely to lead to the discovery of admissible evidence.

Plaintiff also seeks evaluations or opinions related to the '952 patent (Request No. 35), but that information would largely be covered by the attorney-client privilege and work-product immunity. To the extent Hetero conducted any non-privileged evaluation of the '952 patent in connection with its research and development of its ANDA Product, however, such information will be produced in response to Request No. 2.

Similarly, Hetero did not agree to produce its organizational charts. An organizational chart does not provide information specific to the people involved in Hetero's proposed ANDA product because it is not so limited. Instead, such information is best located in the ANDA, which includes the names of those individuals involved in the product-at-issue. At the parties' meet and confer, Plaintiff appeared to have not yet reviewed Hetero's ANDA, however, and thus could not explain what additional information it was seeking beyond the detailed identification of relevant individuals in the ANDA itself. Instead, Plaintiff relies upon a case that is inapposite because it is unrelated to ANDA litigation and addresses claims of fraud and various breaches—not patent infringement. *Sanghavi v. Navient Corp.*, 2020 U.S. Dist. LEXIS 91290, at *5-6 (D.N.J. May 22, 2020).

The interrogatories are similarly flawed, seeking decisions regarding the ANDA prior to its filing (Interrogatory No. 1), other cyclophosphamide products considered beyond the product in the ANDA, which Hetero agreed to provide (Interrogatory No. 3), and the details regarding awareness of and investigations into the '952 patent (Interrogatory Nos. 5 and 6). None of these interrogatories are relevant to determining whether Hetero's ANDA Product infringes or whether the patents are invalid. *Par Pharm., Inc. v. Eagle Pharms., Inc.*, 44 F.4th 1379, 1383 (Fed. Cir. 2022) (the infringement inquiry "is controlled by the ANDA specification itself."). Plaintiff also seeks the details underlying the Paragraph IV certification and Notice Letter (Interrogatory No. 7), and efforts to determine infringement (Interrogatory No. 8), but these requests directly seek information covered by the attorney-client privilege and work-product immunity and have minimal relevance at best. *Cf. Celgene Corp. v. Mylan Pharms. Inc.*, 17 F.4th 1111, 1122 (Fed. Cir. 2021) ("Under § 271(e)(2), submitting an ANDA is the act of infringement. And although the ANDA applicant must later send a notice letter and inform the FDA of the letter's receipt, that all happens after the infringing submission.").

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For the foregoing reasons, Hetero respectfully requests that the Court deny the relief requested in Plaintiff's discovery letter.

Respectfully,

/s/ Kenneth L. Dorsney

Kenneth L. Dorsney (#3726)

cc: All Counsel of Record (via CM/ECF and electronic mail)